

### **REMARKS**

Claims 1-5, 10-13, 15, 17-21 and 23-46 are pending in the application. Claims 6-9, 14, 16 and 22 are cancelled. Claims 2-4, 12-13, 15, 20-21, 24-25, 27-30, 33-38, and 44-45 are listed by the Examiner as withdrawn. Claim 1 is amended to add further description, for example, from paragraph 35 of the specification. Thus, Claims 1, 5, 10, 11, 17-19, 23, 26, 31, 32, 39-43 and 46 are presently under examination.

It is believed that the Claims as amended by reason of the amendment to Claim 1 now even more clearly distinguish over the cited references. The following comments are offered to expedite the allowance of the case.

#### **Comments on OGLE**

The present invention provides:

*A medical article comprising:*

- (a) an adhesive region comprising an adhesive;*
- (b) a therapeutic agent, wherein at least a portion of said therapeutic agent is adhered to a surface of said adhesive region; and*
- (c) microparticles, at least a portion of which are attached to said surface of said adhesive region, wherein said therapeutic agent is neither partially nor fully embedded within the microparticles and wherein the microparticles create pockets which are occupied by the therapeutic agent and from which the therapeutic agent is released.*

In contrast to the present invention, Ogle et al (U.S. Patent Number 6,491,617) ("OGLE") does not teach or suggest the current invention for at least the following reasons:

- 1) OGLE does not use microparticles attached to a surface of an adhesive region, particularly where a therapeutic agent is neither partially nor fully embedded within the microparticles and wherein the microparticles create pockets which are occupied by the therapeutic agent and from which the therapeutic agent is released.
- 2) OGLE does not use an adhesive region comprising an adhesive. OGLE uses binding interactions of the exogenous storage structures to the biocompatible material such as covalent binding interactions to target specific structures within the material (see col.12, lines 25-57). Some of these interactions to tissues require specific pH conditions.

- 3) OGLE does not use a therapeutic agent adhered to the surface of an adhesive region, particularly where the therapeutic agent is neither partially nor fully embedded within microparticles.

### **Comments on PINCHUK**

The present invention is distinguishable over Pinchuk et al (U.S. Patent No. 6,545,097) ("PINCHUK"). PINCHUK relates to compositions comprising a therapeutic-agent-loaded block copolymer that are useful for delivery of a therapeutic agent and to biocompatible block copolymer materials useful, for example, in connection with intravascular or intervascular medical devices (Detailed Description of the Invention, first paragraph). Once synthesized, the block copolymers of PINCHUK can be used, for example, to provide therapeutic-agent-loaded block copolymer compositions for therapeutic agent delivery, or to provide biocompatible intravascular or intervascular devices.

Like OGLE, PINCHUK does not use microparticles attached to a surface of an adhesive region, particularly where a therapeutic agent is neither partially nor fully embedded within the microparticles and wherein the microparticles create pockets which are occupied by the therapeutic agent and from which the therapeutic agent is released. PINCHUK does not discuss the use any type of adhesive, particularly as an adhesive relates to a therapeutic agent or microparticles.

PINCHUK is cited as allegedly teaching a layer for use over a therapeutic agent and microparticles. However, in contrast to the present invention, PINCHUK uses a separate sheath structure and not the layer of the present invention. This point is supported by the description of the term "layer", in paragraph 25 of the current specification which defines the term as follows:

*As used herein a "layer" of a given material is a region of that material whose thickness is small compared to both its length and width. As used herein, a layer need not be planar, for example, taking on the contours of an underlying substrate. Layers can be discontinuous (e.g., patterned). Terms such as "film," "layer" and "coating" may be used interchangeably herein.*

Thus, as used in the current invention, a sheath would not be included in the definition of "layer".

Additionally, any attempt to combine PINCHUK with OGLE must fail. OGLE does not even mention the optional use of any additional coating on its devices. The technology of OGLE is based on the storage and release of the described agents by direct application of the medical device against the adjacent wall (OGLE, Abstract). This description in OGLE may be viewed as teaching away from the use of any additional layer, much less the sheath of PINCHUK. Any assertion by the Examiner that a layer could be used with OGLE is only unsupported speculation.

### **CONCLUSION**

Applicants submit that Claims 1, 5, 10, 11, 17-19, 23, 26, 31, 32, 39-43 and 46 are in condition for allowance. Reconsideration is requested and an early Notice of Allowance is requested.

Should the Examiner be of the view that an interview would expedite consideration of this Response or of the application at large, the Examiner is requested to telephone the Applicant's attorney at the number listed below in order to resolve any outstanding issues in this case.

Respectfully submitted,

Attorney for Applicant  
Mayer & Williams, PC  
251 North Avenue West, 2<sup>nd</sup> Floor  
Westfield, NJ 07090  
Tel.: 908-518-7700  
Fax: 908-518-7795

/ Rosemary M. Miano/  
Rosemary Miano  
Registration No. 29, 674

Dated: August 10, 2009